

**4. 510(k) Summary**

*Submitted by:* The Procter & Gamble Company  
6110 Center Hill Avenue  
Cincinnati, OH 45224

*Contact Person:* Mark M. Anderson, Regulatory Affairs Manager  
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*Date Summary Prepared:* 11 April 2001

*Trade Name:* TAMPAX® Satin Scented Tampons & TAMPAX® Scented Tampons

*Common Name:* Scented Menstrual Tampon

*Classification Name:* Scented or Scented Deodorized Menstrual Tampon  
(per 21 CFR 884.5460)

*Predicate Devices:* TAMPAX® Satin Touch Deodorant Tampons,  
Procter & Gamble, K952344  
TAMPAX® Satin Tampons, TAMPAX® Tampons  
Procter & Gamble, K002096

*Device Description:* The device is a conventional scented menstrual tampon consisting of an absorbent pledget, a withdrawal cord, and a flushable paper applicator.

- The absorbent pledget consists of a rectangular pad of layered cotton and rayon fibers. The pad is overwrapped with a non-woven rayon material, and a cotton withdrawal cord is sewn to the pad with cotton thread. Fragrance is applied to the pad, and the pad is compressed into a traditional bullet-shaped pledget.
- The formed pledget is inserted into a flushable paper applicator consisting of an outer insertion tube and an inner pusher tube. For TAMPAX® Satin Scented Tampons, flexible petals form a closed, rounded tip at the distal end of the outer applicator tube. For TAMPAX® Scented Tampons, the distal end of the outer applicator tube is open.
- Each tampon is wrapped in an individual paper wrapper and packaged in sealed multi-unit containers for retail sale.

*Intended Uses:* The device is intended to be inserted into the vagina to absorb menstrual fluid.

*Technological Characteristics:* The device is similar to the predicate devices in terms of component materials, overall design (see *Device Description*, above), and labeling. This device differs from the K952344 predicate device in the composition of the fragrance.

*Safety Assessment:* Minor compositional differences between the fragrance formulation of one of the predicate devices and the fragrance formulation of the 510(k) device were assessed. The fragrance formulation of the predicate device had been extensively safety tested and used successfully in marketed tampons. The toxicological assessment of the compositions of these fragrance formulations supports the conclusion that the 510(k) device is equally as safe as the predicate devices.

*Effectiveness:* TAMPAX® Scented Satin Tampons and TAMPAX® Scented Tampons comply with the requirements of 21 CFR 801.430. Therefore, additional testing of these tampons is not necessary to establish their equivalence to the predicate tampons in terms of effectiveness.

*Conclusions:* The results of evaluations of this device support the conclusions that it is safe for its intended use and that it is substantially equivalent to the cited predicate devices with regard to safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL - 2 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mark Anderson, Ph.D.  
Regulatory Affairs Manager  
Procter & Gamble Company  
Feminine Care Global Business Unit  
6110 Center Hill Avenue  
CINCINNATI OH 45224

Re: K011171  
Tampax Scented & Satin Scented Tampax-Junior,  
Regular, Super and Super Plus Menstrual Tampon  
Dated: April 11, 2001  
Received: April 17, 2001  
Regulatory Class: II  
21 CFR §884.5460/Procode: 85 HIL

Dear Dr. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

**3. Statement of Indications for Use**

510(k) Number (if known): K011171

Device Name: TAMPAX® Satin Scented Tampons & TAMPAX® Scented Tampons

Indications for Use:

TAMPAX® Satin Scented Tampons & TAMPAX® Scented Tampons are scented menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

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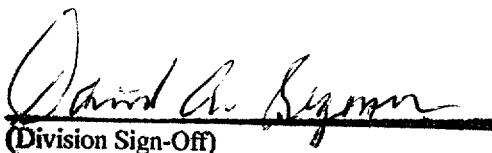
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☒

(Optional Format 1-2-96)

  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K011171